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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,025	10/19/2006	Dennis L. Panicali	701281	3646

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LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	**PAPER NUMBER**
1632	
MAIL DATE	**DELIVERY MODE**
11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,025	PANICALI ET AL.	
	Examiner	Art Unit	
	WU-CHENG Winston SHEN	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The claim amendments filed on 05/11/2006 have been entered. Claims 6, 11, 14, 17 are amended. Claims 1-44 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1 and 6-22, drawn to a method for inducing an immunological response against a malignant pancreatic cell in an individual, said method comprising the steps of: selecting an individual having malignant pancreatic cells or at risk for developing such a pancreatic tumor, administering to the individual a first vector containing a first gene, or antigenic portion thereof, that encodes a pancreatic tumor-associated antigen (PTAA), and at regular intervals thereafter administering at least a second vector containing a gene encoding PTAA or antigenic portion thereof, wherein the PTAA is selected from the group consisting of carcinoembryonic antigen (CEA), mucin (MUC), ras, gastrin, erbB2,

interferonα, tumor necrosis factor-α, hMP-9 immunotoxin, antigenic portions thereof, and modified versions thereof.

II. Claims 2-5, drawn a method for inducing an immunological response against a malignant pancreatic cell in an individual, said method comprising the steps of: selecting an individual having malignant pancreatic cells or at risk for developing such a pancreatic tumor, administering to the individual a first vector containing a first gene, or antigenic portion thereof, that encodes a pancreatic tumor-associated antigen (PTAA), and at regular intervals thereafter administering at least a second vector containing a gene encoding PTAA or antigenic portion thereof, wherein the PTAA is selected from the group consisting of carcinoembryonic antigen (CEA), mucin (MUC), ras, gastrin, erbB2, interferonα, tumor necrosis factor-α, hMP-9 immunotoxin, antigenic portions thereof, and modified versions thereof, and further comprising administering granulocyte- macrophage colony stimulating factor (GM-CSF) as a co-stimulatory molecule.

III. Claims 23-25, drawn to a kit for enhancing a protective immune reaction against a pancreatic tumor comprising at least one pox vector encoding at least two PTAAs or antigenic portion thereof.

IV. Claims 26-32, drawn to an isolated nucleic acid molecule encoding a Muc-1 fragment sufficient to generate an immune reaction to Muc-1.

V. Claim 33, drawn to an isolated nucleic acid molecule encoding one or more of SEQ ID NO: 1, SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4, or a fragment or variant thereof.

VI. Claims 34-40, drawn to a method for inducing an immunological response against a malignant pancreatic cell in an individual, comprising administering a therapeutically effective amount of a nucleic acid molecule encoding a Muc-1 fragment sufficient to generate an immune reaction to Muc-1.

VII. Claim 41, drawn to a method for inducing an immunological response against a malignant pancreatic cell in an individual, comprising administering a therapeutically effective amount of one or more of SEQ ID NO: l, SEQ 1D NO:2, SEQ ID NO:3, or SEQ ID NO:4, or a fragment or variant thereof.

VIII. Claims 42-44, drawn to a kit for enhancing a protective immune reaction against a pancreatic tumor comprising one or more of SEQ ID NO: l, SEQ ID NO:2, SEQ ID NO:3, or SEQ ID NO:4, or a fragment or variant thereof and instructions for use.

(a). Each Group of Groups I and II is subjected to <u>further restrictions</u> to *a specific combination of* (i) <u>the first PTAA</u> selected from the group consisting of carcinoembryonic antigen (CEA), mucin (MUC), ras, gastrin, erbB2, interferonα, tumor necrosis factor-α, hMP-9 immunotoxin, antigenic portions thereof, and modified versions thereof, and (ii) <u>the second PTAA</u> selected from the group consisting of carcinoembryonic antigen (CEA), mucin (MUC), ras, gastrin, erbB2, interferonα, tumor necrosis factor-α, hMP-9 immunotoxin, antigenic portions thereof, and modified versions thereof. Each of the listed PTAA is encoded by a distinct gene and the structure and function of each of the listed PTAA is distinct one from another. It is noted that if an antigenic portion or a modified versions of each of the first PTAA and the second

PTAA is elected for the specific combination, an election of a specific fragment or a specific modification of the elected antigen is required. This is not a requirement for election of species.

(b). Each Group of Groups V, VII and VIII is subjected to the further restrictions to one of the following sequences (i) SEQ ID NO:1 (1548 nucleotides, coding sequences of human MUC 1), (ii) SEQ ID NO:2 (515 amino acid residues, human MUC1 polypeptide), (iii) SEQ ID NO:3 (2106 nucleotides, coding sequences of human CEA, 701 amino acid polypeptide), (iv) SEQ ID NO: 4 (371 amino acid residues, human CEA, amino acid residues 331-701 fragment of CEA), (v) a specific fragment or variant of SEQ ID NO:1, (vi) a specific fragment or variant of SEQ ID NO:2, (vii) a specific fragment or variant of SEQ ID NO:3, (viii) a specific SEQ ID NO a specific fragment or variant of SEQ ID NO:4, or (ix) a specific combination of (i)-(viii) listed above. This is not a requirement for election of species.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, the Commissioner has stated that, "The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of

these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371." See Examination of Patent Applications Containing Nucleotide Sequences 1316 OG 122 (March 27, 2007). **For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.**

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed polynucleotide sequences, the Markush group shall be regarded as being of similar nature when: (A) all alternatives have a common property or activity and (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or (B)(2) in cases where the common structure cannot be the unifying criteria; all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant sequences are considered to be each separate invention for the following reasons:

The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. Each nucleic acid molecule encodes a distinct antigen, which is distinct in structure and function, and requires different processes of excitation and emission for detection. The sequences do not meet the criteria of (B) (1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the nucleic acid sequences, and the polypeptide sequences encoded thereby, of the instant application is lacking and each nucleic acid sequence claimed is considered to constitute a special technical feature.

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Applicant's claims encompass multiple inventions, multiple products (nucleic acid and protein) and multiple methods (methods of using the products for inducing immunological response), and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups is a MUU-1 polypeptide encoded by a nucleic acid molecule.

However, this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art. **Taylor-Papadimitriou et al.** teaches that the MUC1 membrane mucin was first identified as the molecule recognized by mouse monoclonal antibodies directed to epithelial cells, and the cancers which develop from them. Cloning the gene showed that the extracellular domain is made up of highly conserved repeats of 20 amino acids, the actual number varying between 25 and 100 depending on the allele. Each tandem repeat contains five potential glycosylation sites, and between doublets of threonines and serines lies an immunodominant region which contains the epitopes recognized by most of the mouse monoclonal antibodies (See abstract, Taylor-Papadimitriou et al., MUC1 and cancer. *Biochim Biophys Acta.* 1455(2-3):301-13, 1999)

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(i) Claim 7: an orthopox virus vector; avipox virus vector; a suipox virus vector; a capripox virus vector; a leporipox virus vector; and an iridovirus vector. These are different species of poxvirus vector with patentably distinct nucleic acid sequences and characteristics as a vector.

(ii) Claim 12: MUC-1, MUC-2, MUC-3, MUC-4, MUC-5AC, MUC-5B, MUC-6, MUC-7, MUC-11, MUC-12, and antigenic portions thereof and modified versions thereof. These are different mucin proteins with patentably distinct amino acid sequences and characteristics as an antigen.

(iii) Claim 20: MVA and NYVAC. These are different attenuated vaccine vector with patentably distinct nucleic acid sequences and characteristics as a vector.

(iv) Claim 24: MUC-1 and mini-MUC. These are different mucin proteins with patentably distinct amino acid sequences and characteristics as an antigen.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

MPEP 1893.03(d) Unity of Invention Rejoinder

5. MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using (Group VII) an allowable product (Group V) should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent

examiner, Peter Paras, Jr. can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wu-Cheng Winston Shen/
Patent Examiner
Art Unit 1632